Proposed Decision Memo for Pulmonary Rehabilitation (CAG-00356N)

Decision Summary

The Centers for Medicare and Medicaid Services (CMS) proposes that the respiratory therapy services identified in the Comprehensive Outpatient Rehabilitation Facility (CORF) as defined in 42 CFR §410.100(e)(1) to (2)(vi) are reasonable and necessary in chronic obstructive pulmonary diseases (COPD) in patients with GOLD classification II or III (moderate or severe) when furnished under a written plan of treatment that considers all respiratory therapy services.

CMS proposes that since the Social Security Act does not expressly define a comprehensive Pulmonary Rehabilitation Program as a part B benefit, and that the evidence is not adequate to draw conclusions on the benefit of individual components of pulmonary rehabilitation, we are not making any proposed national coverage determinations about these services at this time.

We are requesting public comments on this proposed determination pursuant to §1862(l) of the Social Security Act. We are particularly interested in comments that include input on the frequency and duration of the respiratory therapy services identified in 42 CFR §410.100(e)(1) to (2)(vi). After considering the public comments and any additional evidence we will make a final determination and issue a final decision memorandum.

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Proposed Decision Memo

TO: Administrative File: CAG 00089R

FROM: Steve E. Phurrough, MD, MPA
Director, Coverage and Analysis Group

Marcel Salive, MD, MPH
Director, Division of Medical and Surgical Services

Susan Harrison, MPP
Lead Analyst, Division of Medical and Surgical Services

Ross J Brechner, MD, MS (Stat), MPH
Lead Medical Officer, Division of Medical and Surgical Services

SUBJECT: Proposed Coverage Decision Memorandum for Pulmonary Rehabilitation (PR) Services

DATE: June 27, 2007

I. Proposed Decision

The Centers for Medicare and Medicaid Services (CMS) proposes that the respiratory therapy services identified in the Comprehensive Outpatient Rehabilitation Facility (CORF) as defined in 42 CFR §410.100(e)(1) to (2)(vi) are reasonable and necessary in chronic obstructive pulmonary diseases (COPD) in patients with GOLD classification II or III (moderate or severe) when furnished under a written plan of treatment that considers all respiratory therapy services.

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II. Background

COPD is a term referring to two lung diseases, chronic bronchitis and emphysema, that are characterized by obstruction of airflow that interferes with normal breathing. Both of these conditions frequently co-exist, so physicians use the term COPD. It does not include other obstructive diseases such as asthma. The National Center for Health Statistics (NCHS) reports that COPD is the fourth leading cause of death in America, claiming the lives of 122,283 Americans in 2003. The number of women dying from the disease has surpassed the number seen in men (NCHS, 2003). The best prevalence data available at present come from the third NHANES (NHANES III), a large national survey conducted in the USA between 1988 and 1994. In the USA, for those aged 25-75 yrs, the estimated prevalence of mild COPD (defined as FEV1/FVC <70% and FEV1 $\geq$80% predicted) was 6.9% and of moderate COPD (defined as FEV1/FVC <70% and FEV1 $\leq$80% predicted) was 6.6%. The prevalence of both mild and moderate COPD was higher in males than females, in Whites than in Blacks, and increased steeply with age (Manino, 2002). In the NHANES III study, COPD (defined as the presence of airflow limitation) was estimated to be present in 14.2% of current White male smokers, 6.9% of exsmokers and 3.3% of never-smokers. Among White females, the prevalence of airflow limitation was 13.6% in smokers, 6.8% in exsmokers and 3.1% in never-smokers.

COPD often has its roots decades before the onset of symptoms (Anto et al., 2001). Impaired growth of lung function during childhood and adolescence, caused by recurrent infections or tobacco smoking, may lead to lower maximally attained lung function in early adulthood (Gold et al., 1996). This abnormal growth, often combined with a shortened plateau phase in teenage smokers, will increase the risk of COPD. The landmark study of the natural history of COPD by Fletcher and Peto reported that the forced expiratory volume (FEV1) declined continuously and smoothly over time, with a slight acceleration of the rate of decline with aging. They showed that nonsmokers lose FEV_1 at a slow rate of approximately 42 mL/y and that in many smokers who are resistant to the deleterious effects of smoking on lung function, FEV_1 declines as slowly as in nonsmokers. In contrast, so-called "susceptible" smokers lose FEV_1 at an accelerated rate and are destined to go on to develop clinically significant airflow obstruction. (Fletcher et al., 1976)

Management of stable COPD (ATS American Thoracic Society Guidelines) is accomplished in part through the following modalities:

1. Smoking Cessation
2. Pharmacological Therapy

1. The medications for chronic obstructive pulmonary disease (COPD) currently available can reduce or abolish symptoms, increase exercise capacity, reduce the number and severity of exacerbations, and improve health status.
2. At present, no treatment is shown to modify the rate of decline in lung function.
3. The change in lung function after brief treatment with any drug does not help in predicting other clinically related outcomes.
4. The inhaled route is preferred.
5. Changes in forced expiratory volume in one second (FEV1) following bronchodilator therapy can be small but are often accompanied by larger changes in lung volume, which contribute to a reduction in perceived breathlessness.
6. Combining different agents produces a greater change in spirometry and symptoms than single agents alone.

3. Long-Term Oxygen Therapy
4. Pulmonary Rehabilitation
5. Nutrition counseling
6. COPD surgery
7. Evaluation and treatment of sleep disorders

In general PR may involve some or all of the following: treatment plans and implementation; medical evaluation; monitoring of progress; counseling and/or education; exercise training; self-management training; nutrition training; and psychosocial support.

III. History of Medicare Coverage

Medicare Coverage for Pulmonary Rehabilitation

Currently, there is no national coverage determination for PR. However, there is limited coverage for some respiratory therapy services provided in a comprehensive outpatient rehabilitation facility (CORF). Various components of PR may be covered at contractor discretion in other settings.

Reconsideration

The American Association of Cardiovascular and Pulmonary Rehabilitation (AACPR), the American College of Chest Physicians (ACCP), the American Thoracic Society (ATS), and the National Association for Medical Direction of Respiratory Care (NAMDRC) formally requested that CMS promulgate an NCD which identifies the components of PR services. The requestors suggest that this NCD should address the provision of these services in the hospital outpatient setting, the physician office setting and the CORF setting.

Benefit Category

There is no specific benefit category for, and no statutory definition of, "pulmonary rehabilitation" under Title XVIII of the Social Security Act (“the Act”). The comprehensive outpatient rehabilitation facility (CORF) benefits may include “respiratory therapy” services and “pulmonary rehabilitation techniques” under a plan of treatment established and periodically reviewed by a physician (sections 1861(cc)(1), 1832(a)(2)(E) of the Act; 42 CFR section 410.100(e)). These CORF services must be furnished by qualified professional personnel as defined in regulation by the Secretary (42 CFR section 410.100).

Other components of PR may be covered in different settings. For instance, physician evaluation and management (E/M) of patients with pulmonary diseases for whom "pulmonary rehabilitation" is contemplated may include an initial evaluation, treatment plan development and implementation, monitoring, and counseling/education regarding all aspects of the disease (42 CFR section 410.20). These E/M services may be considered to be a benefit as physicians' services under 1861(s)(1) of the Act.

There may be a benefit category for therapeutic exercise under certain circumstances. For instance, therapeutic exercise may be considered to be a benefit under section 1861(p) of the Act as a physical therapy service.

Physicians are authorized by section 1861(q) of the Act to furnish certain counseling services. Nurse practitioners, clinical nurse specialists, and physician assistants are also authorized by sections 1861(s)(2)(K)(ii) and (s)(2)(K)(i), respectively, of the Act to furnish services that would be physician services if performed by a physician that may include counseling services (42 CFR sections 410.75(c), 410.76(c), 410.74(a)(1)). Qualified psychologist services, which may often include counseling services, are authorized by section 1861(s)(2)(M) of the Act (42 CFR section 410.71). Counseling may be considered to be a benefit under section 1861(s)(2)(A) of the Act as “incident to” a physician service. If counseling services are related to a mental health diagnosis, then Clinical Social Workers are authorized by section 1861(s)(2)(N) of the Act to furnish diagnostic and therapeutic mental health services that may include therapy services.

There is no general benefit category for nutritional counseling. We do not pay for the services of a registered dietician or professional nutritionist except under specified circumstances. Under section 1861(vv) of the Act, medical nutrition therapy is a covered benefit when furnished by a registered dietitian or professional nutritionist for certain individuals. The benefit covers nutritional diagnostic, therapy, and counseling services for the purpose of disease management for beneficiaries who are diabetic or have a renal disease, when a referral is made by a physician. It also allows registered dietitians and professional nutritionists to receive direct Medicare payment (42 CFR section 410.132). Under section 1861(s)(1) of the Act, physicians are authorized to furnish physician services that may include diet counseling. Diet counseling may be considered to be a benefit under section 1861(s)(2)(A) of the Act, “incident to” physician services.

All services furnished under the Medicare program must be medically reasonable and necessary, and appropriate for diagnosis and/or treatment of an illness or injury. By regulation, services furnished as part of a maintenance program involving repetitive activities that do not require the skilled services of nurses or therapists are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (42 CFR section 410.102(b)). Furthermore, physicians and nonphysician practitioners must be authorized/licensed by the State in which the services are furnished to render the services.

IV. Timeline

December 27, 2006	CMS accepts the American Association of Cardiovascular and Pulmonary Rehabilitation (AACPR), the American College of Chest Physicians (ACCP), the American Thoracic Society (ATS), and the National Association for Medical Direction of Respiratory Care's (NAMDRC) formal request that CMS promulgate an NCD which identifies the components of PR services. The requestors suggest that this NCD should address the provision of these services in the hospital outpatient setting, the physician office setting and the CORF setting.
January 27, 2006	Initial 30-day public comment period closes.
June 27, 2007	Proposed decision memorandum is posted and the 30-day public comment period begins.

V. FDA Status

Not Applicable.

VI. General Methodological Principles

When making national coverage decisions, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

A detailed account of the methodological principles of study design that the agency utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendices. In general, features or clinical studies that improve quality and decrease bias include the selection of a clinically relevant cohort, the consistent use of a single good reference standard, and the blinding of readers of the index test, and reference test results.

Public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination. Public comments that contain personal health information will not be made available to the public. CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum.

VII. Evidence

A. Introduction

This summary represents the body of evidence for PR for chronic obstructive pulmonary disease (COPD), asthma, bronchiectasis, ventilator dependency and other diseases in Medicare Beneficiaries. Health outcomes of interest to CMS for these indications include changes in mortality, modifiable risk factors, quality-of-life measures, and intermediate psycho/physiologic outcomes. Some of the common outcome measures examined in PR are Quality of life (QoL), functional exercise capacity, survival, and Activities of Daily Living (ADLs). Disease-specific QoL in COPD patients is commonly measured with the St George's Respiratory Questionnaire (SGRQ) and Guyatt's Chronic Respiratory Questionnaire (CRQ). Common measures of exercise capacity are the 6-minute walking distance (6MWD, expressed in meters) and the Shuttle Walking Test (SWT) that requires patients to walk at increasing speeds up and down a 10m course.

We also reference the GOLD (GOLD 2001) classification of COPD. This system classifies COPD patients into 3 classes as follows:

I: Mild COPD = FEV1/FVC < 70%, FEV1 ≥ 80% predicted.
With or without chronic symptoms (cough, sputum production)
II: Moderate COPD = FEV1/FVC < 70%, FEV1 ≥30% to ‹80% predicted
IIa: FEV1 ≥ 50% to < 80% predicted
IIb: FEV1 ≥ 30% to < 50% predicted
With or without chronic symptoms (cough, sputum production, dyspnea)
III: Severe COPD = FEV1/FVC < 70% FEV1 < 30% predicted or FEV1 < 50% predicted plus respiratory failure or clinical signs of right heart failure

This National Coverage Analysis (NCA) focuses on the following question:

- In persons age 65 years and older, is the evidence sufficient to conclude that PR and/or its components will improve health outcomes for COPD or other indications in the home, outpatient and CORF settings?

B. Discussion of evidence reviewed

1. Literature Search

CMS searched the Cochrane Library and Pubmed (1995 to present) databases for systematic reviews and technology assessments of pulmonary rehabilitation as well as randomized clinical trials (RCTs) evaluating pulmonary rehabilitation for persons 65 years of age and older. General keywords included pulmonary rehabilitation and randomized control trials. Studies must have presented original data, included ≥ 10 patients in each arm and been published in peer-reviewed English language journals. Abstracts were excluded.

2. External technology assessments

Cochrane Collaboration Review of Pulmonary Rehabilitation (PR) for COPD (2006)

This Cochrane meta-analysis was based on 31 RCTs for which health-related quality of life (QoL) and/or functional exercise capacity (FEC) or maximal exercise capacity (MEC) were measured in patients with COPD. This updated Cochrane collaboration review states that the primary conclusions of their prior review in 2001 were essentially strengthened in this update and they addressed several new issues. They concluded that there was significant benefit from respiratory rehabilitation including at least four weeks of exercise training as part of the spectrum of management for patients with COPD. The authors also found clinically and statistically significant improvements in the important domains of quality of life, including dyspnea, fatigue emotional function and mastery. Lastly they found that when compared with the treatment effect of other important modalities of care for patients with COPD such as inhaled bronchodilators or oral theophylline and its new derivatives, pulmonary rehabilitation resulted in greater improvements in important domains of health-related quality of life and functional exercise capacity.

AHRQ Technology Assessment of Pulmonary Rehabilitation for COPD and other lung diseases (2006)

This Technology Assessment defined PR as any intervention that included an exercise-training component of at least two weeks' duration and optionally one or more non-exercise components: educational, psychosocial support, breathing exercises, respiratory muscle training, or nutritional interventions. The TA analyzed 44 RCTs included in three published systematic reviews, and 26 additional RCTs that had not been assessed by these reviews. One of the inclusionary requirements was that the average age of participants was 59 years or more, while another was that the intervention contained an exercise regimen of at least two weeks duration.

The AHRQ TA excluded RCTs when the non-exercise PR components of the RCT were considered supplemental interventions. These were defined as pharmacological (e.g., O_2 supplementation during exercise, tiotropium administration during the PR etc.), nutritional (e.g. polyunsaturated fatty acids administration) or other interventions (e.g. ventilation support) aiming to facilitate or enhance the effects of exercise training.

Since PR cannot generally reverse the derangement of pulmonary mechanics (as assessed by FEV_1, other lung volumes and lung capacities) changes in pulmonary physiologic measurements were not reviewed in the TA.

The AHRQ TA utilizes the GOLD classification for COPD and we have utilized that classification in our NCD.

The authors concluded that exercise-based PR is effective in improving the patients' disease-specific QoL, as well as their functional and maximal exercise capacity. This was especially true in the short term (weeks to months) where the improvements were significant. Exercise-based PR interventions may reduce hospitalizations and primary care consultations. There is evidence supporting exercise-based PR among patients recovering from or recently recovered from acute exacerbations of COPD. The RCTs and meta-analyses did not provide evidence on the safety of PR interventions nor point out which co-morbid conditions predispose patients to or protect patients from adverse events. There is insufficient evidence to draw robust conclusions on whether exercise training has an incremental impact when added to non-exercise PR components like education or inspiratory muscle training. The authors reported not finding statistically significant differences when comparing exercise training alone with non-exercise components alone, and they did not find statistically significant differences when assessing the incremental impact of non-exercise components added to exercise training. Lastly, none of the above results translated to improved survival, at least among patients with stable COPD.

As a final comment the authors stressed that all the aforementioned results should be viewed with caution because they are based on relatively few studies of substantial sample size with good methodological strength.

3. Internal technology assessment

CMS independently searched PubMed for randomized controlled trials and selected trials in which PR was utilized. In this section, we do not review the studies that were extensively reviewed in the TAs above. Twelve relevant RCTs not included in the TAs were identified and are summarized below.

Interventions Involving Exercise

Intervention: nurse-assisted patient education and self-management, and follow-up.
Setting: home

Coultas et al. (2005)

This study was aimed at measuring the effect of increasing access to selected components of PR in COPD patients, namely patient education, enhanced follow-up, and enhanced patient self-management skills over a six-month period. The three arms were medical management (MM), nurse-assisted collaborative care (CM) and usual care (UC) with 51, 49, and 51 patients completing the study in each arm respectively (out of 217 enrollees total). Patients all had a $\geq$20 pack-year smoking history and were all $\geq$ 45 years of age with an average age of 69 years. There were no significant differences in demographics at baseline with the exception of age ($p<0.05$) being higher in the control group, though educational level approached significance ($p<0.07$, group data not shown). Outcomes were measured via the SF-36 and disease-specific SGRQ questionnaires. Findings demonstrated no significant differences when comparing the results of the three arms. Authors concluded that interventions in patient education, enhanced follow-up, and enhanced patient self-management skills in patients with COPD do not result in clinically meaningful improvements in health-care status and self-reported health care utilization. The large number of enrollees that dropped out of each group may have made the results skewed since they had more severe airflow obstruction, higher distress levels and lower QoL than the patients who completed the study. Data on demographics were not reported.

Intervention: low- and middle-intensity PR exercise programs
Setting: home
Bjornshave et al. (2005)

This report compared two frequencies of home-based training over a four-week period in 20 patients with moderate to severe COPD over an 18 month enrollment period. The original group was 124 patients of whom 65 were selected and only 20 accepted, nine in one group and 11 in the other (lower intensity) group. Demographic analysis showed no significant differences between the different arms on sex, age, and BMI, the only demographic characteristics listed in the paper. The outcome measured was walking time in seconds on a standardized treadmill test. Middle-intensity was significantly improved over low-intensity in percent improvement (55% versus 20%, $p<0.001$). The authors concluded that middle-intensity training increases the physical working capacity for patients.

Intervention: individually tailored walking and arm exercise in housebound COPD patients.
Setting: home
Boxall A et al. (2005).

Sixty homebound patients ≥ 60 years of age with COPD were studied over 12 weeks with either an individually tailored supervised walking and arm-exercise program plus patient education, or no intervention (until 12 weeks later for ethical reasons). Patient demographics comparisons showed no significant differences between study arms at the end of 12 weeks. Outcomes were measured by 6MWT results, the St. Georges Respiratory questionnaire and the Borg subjective breathlessness score. Significant results were an improvement in the Borg score ($p<0.024$), the St. Georges respiratory questionnaire score ($p<0.020$), and the 6MWT of the intervention group ($P<0.023$) as compared to the control group. At six months the intervention group demonstrated a shorter hospital length of stay (LOS) for readmission with exacerbation ($P<0.035$). The authors concluded that a 12 week home-based PR program is effective in improving exercise intolerance, subjective breathlessness, and QoL for housebound elderly COPD patients.

Intervention: PR for 4 weeks versus 7 weeks.
Setting: Outpatient
Green RH et al. (2001)

In this RCT forty four persons with COPD, 28 men and 16 women, average age 68, completed either a four week (N=23) shortened PR program or a conventional seven week PR program (exercise and disease education). The two groups were not statistically different on demographic characteristics. The subjects were measured before and after intervention on the CRQ (the primary outcome variable), the Breathing Problem Questionnaire (BPQ), the shuttle walking test (SWT) and the treadmill endurance test (TET). Clinical and statistical significance was reached for the total CRQ score in favor of the seven-week group ($p<0.05$) and its domains for dyspnea ($p<0.05$), emotion ($P<0.005$) and mastery ($P<0.05$). The authors concluded that a seven-week PR program provides greater benefits than a four-week PR program in terms of health status.

Intervention: Dyspnea management (DM) versus DM plus supervised exercise training.
Setting: Outpatient

Carrier-Kohlman et al. (2005)

In this RCT 103 patients (average age 66, F:M ratio=57:46) were randomized to one of three arms consisting of dyspnea self-management only (DM=individualized education and demonstration of dyspnea self-management strategies and bi-weekly nurse telephone calls), DM plus four supervised exercise sessions (DME) or DM plus 24 supervised exercise sessions (DMT). Outcomes were measured every two months for one year and consisted of dyspnea degree (Borg test) during incremental treadmill testing and on exercise performance on incremental and endurance treadmill tests at six and 12 months. Dyspnea on ADL and self -reported physical functioning (CRQ, SF-36) improved for all groups with DMT better than DME or DM as time went on. This was attributed by the authors to continuing supervised exercise sessions. DME and DMT were not significantly different from DM or each other at the end of one year. The authors reported missing data on 24 of 103 patients and an additional 12 patients dropped out before the first two-month period. The authors concluded that the greater the number of supervised exercise training sessions, the more improved ADLs and physical functioning would be for patients with COPD.

Intervention: Nutritional enhancement of exercise plus PR versus PR
Setting: Outpatient
Steiner MC et al. (2003)

In this study 85 persons with COPD were randomized to receive a carbohydrate supplement or non-nutritive placebo daily during a seven-week outpatient PR program (endurance, low impact conditioning, education). There was no statistically significant difference between groups on demographics at baseline with average age of 66-68 years and F:M ratio approximately 3.5:5 in both groups. Peak and submaximal exercise performance as well as walk tests, health status, body composition, muscle strength and macronutrient intake were measured. The results showed that both groups increased walking and health status significantly but the improvement in incremental shuttle walking test performance was significantly greater in the supplemented group ($P<0.05$). The placebo group lost weight while the treatment group gained weight. The authors concluded that exercise training results in negative energy balance that can be overcome by nutritional supplementation.

Intervention: drugs only versus drugs plus intensive PR

Setting: Outpatient
Guell R et al. (2006)

The impact of PR on psychosocial morbidity in patients with severe COPD was studied in this RCT where both arms were treated with salbutamol, ipatropium bromide, and inhaled budespniode (before admission to the trial), and one arm had additional intensive PR for four months (relaxation, various breathing exercises, chest and abdominal wall exercise). Forty male COPD patients with a mean age of 65, all having severe chronic outflow limitation, were randomized to a control group or to a PR group. Five dropped out leaving 18 in the intensive PR group and 17 in the control group. Outcome measures were psychological assessment using the MHBI (Million Behavioral Health Inventory), the Revised Symptom Checklist (SCL-90-R), the 6MWT, and the Chronic Respiratory Questionnaire (CRQ) for HRQL. At four months the PR group showed statistically significant improvements relative to the control group on the MBHI in selected scales of personality (forceful, sensitive, introversive and chronic tension $P<0.05$). The PR group also had statistically significant improvements relative to the control group on the SCL-90-R, in the selected scales of somatization, depression, anxiety, hostility, and total score ($p<0.01$), and in HQRL as measured by the CRQ, in the domains of dyspnea ($p<0.01$), and mastery ($P<0.05$). Finally, the PR group showed a statistically significant improvement in the 6MWT with a 63 meter increase as compared to a 22 meter decrease in the control group ($p<0.01$). The authors concluded that PR may decrease psychosocial morbidity in COPD patients even when no specific psychological intervention is performed. They also reiterated that PR has a positive impact on functional exercise capacity and HRQL.

Interventions Involving Counseling with or without PR

Intervention: individual counseling plus PR versus PR alone in COPD patients
Setting: Outpatient
De Blok et al. (2006)

This RCT in COPD patients studied the effects of a lifestyle physical activity counseling program in addition to a PR program (exercise training, dietary intervention, psycho-educational modules) versus the PR program only. Measurement with a pedometer during PR in 21 patients with COPD was studied in this pilot RCT (ten in the intervention group and 11 in the PR only group). Demographic characteristics were not reported in the paper except to say that patients were between 40 and 85 years of age, and from all stages of COPD. The primary outcome was the number of steps per day as measured by a pedometer. Secondary outcomes measured were depression status, HRQL, ADL, and self-efficacy. No statistically significant findings were reported though the exercise counseling group showed a p value of 0.11 in steps per day increase after nine weeks of the program. The intervention group wore the pedometer for ten weeks and the control group only the first and last weeks. The authors concluded, in spite of the very small sample sizes with resulting inability to correct for confounding variables, that the use of a pedometer is a feasible addition to PR with resulting improvement in outcome and maintenance of PR results.

Intervention: PR plus psychotherapy versus PR only
Setting: Outpatient
De Godoy et al. (2003)

An intervention group of 14 persons with COPD attended a PR program (physical exercise, physiotherapy, education) with one psychotherapy session per week and the control group (CG) of 16 persons had the same PR without psychotherapy in this RCT to test for the effect of psychotherapy on anxiety and depression in COPD. The patients averaged 60+ years of age and demographic differences between groups were not significant, apparently due to the small sample size (TG 14, CG 16). Males comprised the majority of both groups. Main outcomes were measured at inception and completion of 12 weeks of therapy using the Beck Anxiety Inventory (BAI) and the Beck Depression Inventory (BDI) as well as the 6MWD. Both groups showed statistically significant improvement on the 6MWD, while only the TG had significant reduction in anxiety ($p<.001$) and depression ($p<0.02$) levels. The authors concluded that including psychotherapy in a PR program for patients with COPD reduced anxiety and depression levels but did not impact 6MWD performance. The potential confounders in this study were not able to be adjusted for due to the small sample size.

Intervention: Shortness of breath education versus education on topics not related to lung disease.
Setting: Outpatient
Sassi-Dambron DE et al. (1995)

In this RCT 98 subjects with COPD were randomized to shortness of breath education for six weeks (education re: pulmonary physiology, COPD, dyspnea, progressive muscle relaxation, breathing techniques, panic control and stress management - TG) or health education on topics not directly related to lung disease (CG) with nine dropouts before treatment (one in the TG), and nine more during the treatment period (five in TG, four in CG). Outcome measures consisted of dyspnea measures (Borg, ATS dyspnea scale, Visual Analog Scale, baseline and transition dyspnea indices, and oxygen cost diagrams), and exercise tolerance (6MWD). At six weeks there was no significant difference between the TG and the CG on any outcome measure. The authors concluded that dyspnea management without structured exercise training or other PR program components does not improve exercise tolerance, dyspnea, HQRL, anxiety or depression.

Intervention: PR versus brief advice or education.
Setting: Outpatient

1) White RJ et al. (2002)

In this RCT 103 patients with COPD were randomized to receive either a six-week PR program two times per week at the hospital or to attend one advice session where they were given educational materials, verbal advice and guidance about exercise. The PR program consisted of walking, step and strengthening exercise plus education with regard to respiratory problem management. At three months they were reassessed on their original tests leading to before-after comparison. The average age in the two groups was 67 years and the M:F ratio was approximately 2:1 in both groups. The TG (N=54) six-minute walking distance increased significantly ($p<0.001$) by 43 meters as compared to 23 meters in the brief advice group (N=49), but there was no difference in the two groups in HRQL as measured by the CRQ. The authors concluded that even a short PR program was beneficial in terms of improved exercise tolerance as compared to brief advice.

2) Ries AL et al. (1995)
Setting: Outpatient

Over an 18 month period 352 patients with COPD were screened and 119 met the inclusion criteria and remained in the study (15 women and 42 men in the TG and 17 women and 45 men in the CG). The average age for the TG was 61 years and for the CG it was 63 years. All were on medical treatment. There were no significant demographic differences between the two groups at study entry. These subjects were then randomly assigned to either comprehensive PR (TG) or an education program (CG) over eight weeks. The PR program consisted of twelve four-hour sessions with education, physical and respiratory care instruction, psychosocial support and supervised exercise training. The education group attended four two-hour educational sessions with no individualized instruction or exercise training. Each subject was pre-and post-tested on physiologic and psychosocial function up to 72 months post intervention. Physiologic tests consisted of pulmonary function, maximum exercise tolerance (MET), endurance exercise and rest and exercise gas exchange. Psychosocial measures consisted of a self-efficacy questionnaire, a quality of well-being scale, the Centers for Epidemiologic Studies Depression Scale (CES-D) and the University of California SD shortness of breath (SOB) questionnaire. Results demonstrated that the eight week PR program produced significantly greater improvement in exercise endurance, MET, symptoms of perceived breathlessness, reported SOB, and self-efficacy for walking (all $p<0.05$). These benefits persisted for between six and 24 months after the intervention. There were no significant differences between groups in pulmonary function, depression or general QoL. The authors concluded that there were definite benefits of pulmonary rehabilitation with COPD in the areas of exercise endurance, MET, symptoms of perceived breathlessness, reported SOB, and self-efficacy for walking in a comprehensive PR program as compared to education only.

4. MEDCAC

Not applicable.

5. Evidence-based guidelines

The joint ACCP/AACVPR Evidence Based Guidelines regarding PR released in May 2007 provides a systematic, evidence-based review of the pulmonary rehabilitation literature that updates the 1997 ACCP/AACPR guidelines. The joint statement strengthens the 1997 recommendations. Specifically, ACCP/AACPR reaffirms health-related QoL improvements for pulmonary rehabilitation patients and supports improvements in health care utilization. The 2007 guidelines introduce new evidence supporting longer term rehabilitation, maintenance strategies following rehabilitation, the incorporation of education and strength training. Additionally, some support for noninvasive ventilation in selected patients with advanced COPD was demonstrated. And current evidence appears to benefit patients with chronic lung diseases other than COPD such as asthma, interstitial disease, bronchiectasis, cystic fibrosis, chest wall diseases, neuromuscular disorders, ventilator dependency, and before and after lung surgery for transplantation, volume reduction, or cancer. The joint statement does point out that current evidence does not support routine inspiratory muscle training, the use of anabolic drugs, nutritional supplementation, routine inspiratory muscle training and supplemental oxygen therapy for patients with severe hypoxemia.

The major national and international respiratory organizations (ATS/ERS, the American College of Chest Physicians [ACCP] jointly with the American Association of Cardiovascular and Pulmonary Rehabilitation [AACVPR], and Global initiative for chronic Obstructive Lung Disease) have recommended PR as the standard of care in the treatment of moderate to severe chronic respiratory disease and these represent GOLD classification II or III (moderate or severe) COPD (Gold 2001).

6. Professional Society Position Statements

The ACCP/AACPVR joint statement states that there is substantial new evidence to support that PR is beneficial for patients with COPD and other chronic lung diseases. They cite current research and opportunities for future research that will possibly advance the current state of knowledge and make PR available to many more eligible patients.

The ATS/ERS joint statement notes that PR has become recognized as a cornerstone in the comprehensive management of patients with COPD. They cite that the evidence for improvement in exercise endurance, dyspnea, functional capacity, and quality of life is stronger for rehabilitation than for almost any other therapy in COPD. Additionally, PR has a favorable influence on systemic effects and comorbidities associated with chronic lung disease. Suggesting that because these impairments are present to some extent in all chronic lung disease PR should be effective in diseases other than COPD. However, they note that more research is needed to optimize the effectiveness of PR and implementation strategies should be aimed at improving availability to all patients needing it, especially through involving health care professionals as to rational, scope and benefits of PR. The statement suggests that adjunctive strategies, such as hormonal therapy, supplemental oxygen administration to non-hypoxemic patients, and noninvasive ventilation, are being developed; but their effectiveness must be established. Additionally, PR effectiveness in respiratory diseases other than COPD must be established through clinical trials. Finally, they note that there exists a need to develop ways to maintain the benefits of PR, especially through improving long-term self-management and adherence to the exercise regimen in the home setting and more concerted efforts are needed to evaluate the effect of PR on survival, because it is entirely possible that it may favorably influence this outcome.

The AARC published a clinical practice guideline for PR. Although the type of supporting evidence is not specifically stated for each recommendation, the guideline is developed from a thorough review of the literature, surveys of current practice, and the expertise of the members of their working group.

The guideline defines PR as a "multi-disciplinary program of care for patients with chronic respiratory impairment that is individually tailored and designed to optimize physical and social performance and autonomy." They acknowledge that PR provides multidisciplinary training to improve the patient’s ability to manage and cope with progressive dyspnea. PR efforts are often focused on patients with chronic obstructive pulmonary disease (chronic bronchitis and/or emphysema), other conditions appropriate for this process include, but are not limited to, patients with asthma, interstitial disease, bronchiectasis, cystic fibrosis, chest wall diseases, neuromuscular disorders, ventilator dependency, and before and after lung surgery for transplantation, volume reduction, or cancer.

PR services include critical components of assessment, physical reconditioning, skills training, and psychological support. Additional PR services may include vocational evaluation and counseling. A PR program must be tailored to meet the needs of the individual patient, addressing age-specific and cultural variables, and should contain patient-determined goals, as well as goals established by the individual team discipline. Both patients and families participate in this training administered by health care professionals. PR services are overseen by a medical director to assure appropriate performance by the program staff and to assure proper service delivery for patients with chronic respiratory disease.

Based on the individualized assessment, areas that should be considered are: pulmonary anatomy and physiology including the pathophysiology of lung disease; description and interpretation of medical tests; bronchial hygiene techniques; exercise conditioning and techniques including: breathing retraining and endurance, strength, and flexibility training of the upper and lower extremities.

Other areas that should be included in the assessment include actions and side-effects of medications including non-prescription products, such as vitamins, over-the-counter medications, and herbal remedies; functional self-management; sleep disturbances; sexuality and intimacy; nutrition; smoking cessation counseling; psychosocial intervention and support; available community services, including patient/family support groups; advance care planning; travel issues; recreation/leisure activities; stress management and indications for oxygen and methods of delivery.

7. Expert Opinion

CMS received no comments identified as expert opinions during the initial 30-day comment period.

8. Public Comments

During the initial public comment period CMS requested public comments and evidence addressing the five following questions:

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- **What is an appropriate definition of pulmonary rehabilitation?**
- **What are the components of pulmonary rehabilitation?**
- **Is pulmonary rehabilitation conducted similarly in all settings?**
- **What are patient outcomes for pulmonary rehabilitation?**
- **Is there adequate evidence, including clinical trials, for evaluating health outcomes of pulmonary rehabilitation in the Medicare population?**

We received a total of 154 public comments, the majority of which did not address any of the aforementioned questions. Comments that directly addressed the five questions we asked included four comments from professional societies, one comment from a voluntary health organization and five comments from hospitals that provide PR services on an outpatient basis.

Comments on the questions, with Evidence

Professional Societies:

The requestor, including ATS, ACCP, NAMDRC and AACVPR and three additional societies including the American Physical Therapy Association (APTA), the American Association for Respiratory Care (AARC), the American Thoracic Society Public Advisory Roundtable (ATS-PAR) and one voluntary health organization, the American Lung Association (ALA) submitted substantive public comments that included evidence and directly addressed the abovementioned questions.

What is the appropriate definition of pulmonary rehabilitation?

With regard to the first question, all of the professional societies except for APTA cite the definition adopted in the ATS and the European Respiratory Society (ERS) 2006 Statement on Pulmonary Rehabilitation:

“Pulmonary rehabilitation is an evidence-based, multidisciplinary, and comprehensive intervention for patients with chronic respiratory diseases who are symptomatic and often have decreased daily life activities. Integrated into the individualized treatment of the patient, pulmonary rehabilitation is designed to reduce symptoms, optimize functional status, increase participation, and reduce health care costs through stabilizing or reversing systematic manifestations of the disease.”

The APTA defines PR as “a multi-disciplinary, multi-setting program of care often including physicians, nurses, respiratory therapists, physical therapists, occupational therapists, psychologists, and social workers. PR programs are used to treat severe COPD, and lung disease. The program is designed to educate and train the patient to achieve optimal function through integrated and specialized treatment.” The ALA refers to a definition included in a 2003 joint petition to CMS where PR services are defined as, “those patient services that are prescribed by a physician and include initial evaluation and goal setting, therapeutic exercise, education, psycho-social support and on going assessment of patient progress. Other diagnostic and therapeutic services appropriate to pulmonary rehabilitation may be required on an individual basis.”

What are the components of pulmonary rehabilitation?

With respect to the second question, the requestor indicates eight components of PR including initial evaluation, exercise training, self-management education, nutritional intervention, psychosocial support, assessment of patient-centered outcomes, staffing component containing a medical director/ licensed physician, and qualifying criteria recommendations. The AARC recommended five criteria comprising of initial evaluation and goal setting, therapeutic exercise, education, physical support, and ongoing assessment of patient progress while recognizing that other services may be required on an individual basis. AARC also stressed the importance of respiratory therapists in providing physician-oriented PR services specifically in components including patient assessment, disease management and exercise supervision. ATS-PAR suggested five components including patient education; exercise training; self-management, maintenance and education; nutrition training and psychosocial support. The APTA proposes eleven criteria including initial evaluation; goal-setting; aerobic conditioning; strength and flexibility training; functional assessment; activity modification; evaluation of need for assistive devices; determination of durable medical equipment needs; education; psycho-social support (including smoking cessation) and on-going assessment of the patient's progress. Again, the ALA refers to components set forth in the 2003 submission, including initial evaluation and goal setting, therapeutic exercise, education, psycho-social support and on going assessment of patient progress. They note that other diagnostic and therapeutic services appropriate to PR may be required on an individual basis.

Is pulmonary rehabilitation conducted similarly in all settings?

The requestor indicates that appropriate settings for PR are hospital outpatient settings, CORFs and physician offices, suggesting that a physician should be immediately available. The ALA did not comment directly on where PR services are conducted, but encourages CMS to take into account reasonable access to services in rural areas of the country and encourages CMS to create a PR coverage policy that allows flexibility so that providers in rural areas can also offer the service. The ATS-PAR suggests that outpatient settings are the primary delivery setting in the United States. APTA indicates that outpatient settings including hospital based clinics, CORFs and physician's offices conduct pulmonary rehabilitation. Also, they suggest that inpatient settings where PR is conducted include hospitals, inpatient rehabilitation centers, Skilled Nursing Facilities (SNFs) and patient homes. The APTA suggests that the structure of a pulmonary rehabilitation program does not change but the interventions and plan of care may vary depending on the severity of the patient's condition. The AARC did not comment on this question.

What are patient outcomes for pulmonary rehabilitation?

The requestor notes that patient centered outcomes should reflect control of symptoms, ability to perform daily activities, exercise performance and quality of life. Additionally, they explain that outcome measures should include symptom evaluation, performance evaluation, exercise capacity and health related quality of life. ATS-PAR explains that outcomes should include improvement in exercise capacity, dyspnea, and quality of life in chronic lung disease patients. The APTA advises that patient outcomes should include incremental exercise tests, walking tests, health status questionnaires, and functional mobility and activities of daily living assessments. ALA refers to the section in the 2003 petition but emphasizes psycho-social improvements experienced by COPD patients who participate in PR programs. The 2003 petition cites outcomes including improved exercise tolerance, decreased hospital days, decreased use of medical resources, improved QoL, reduction of respiratory symptoms, more independence, improvement in psychological function with less anxiety and depression. As a note, AARC did not respond to this question.

Is there adequate evidence, including clinical trials, for evaluating health outcomes of pulmonary rehabilitation in the Medicare population?

Both the requestor and the ALA cite references as evidence for evaluating health outcomes of PR in the Medicare population. CMS has included all RCTs in the evidence section of this document.

Hospitals:

Five hospitals submitted identical public comments.

What is the appropriate definition of pulmonary rehabilitation?

All of the hospitals define PR as “an outpatient treatment modality directed primarily at patients with Chronic Obstructive Pulmonary Disease (COPD) including chronic bronchitis, asthma and emphysema. PR provides functionally discrete, comprehensive, physician-directed outpatient services that are interdisciplinary and outcome oriented. Candidates for receiving services are individuals with pulmonary disease that can benefit and sustain gains from an intense therapeutic and rehabilitative treatment regimen.”

What are the components of pulmonary rehabilitation?

All of the hospitals suggest that the essential components of PR are assessment, patient education and training, therapeutic exercise and activities including breathing retraining, bronchial hygiene and aerosol medications, activities of daily living, clinical monitoring of pulmonary functioning, psychosocial intervention and after care. Additionally, they note that prevention strategies are integrated into every aspect of the services.

Is pulmonary rehabilitation conducted similarly in all settings?

The five hospitals outline how PR is conducted in an outpatient hospital setting. They note that PR programs integrate a number of health-care disciplines including physical therapy, occupational therapy, respiratory therapy, nursing, dietary services, pharmacology, and psychosocial services that tailor treatment services to the specific needs of each patient. All hospitals suggest that their PR services are provided under physician direction and supervision under the “incident to” provision of the Medicare statute. Also, all hospitals outline their entry criteria, exclusionary criteria, medical necessity criteria, discharge criteria, physician orders, assessment and evaluation, treatment planning, progress notes, discharge plan, and coding and billing for PR services.

What are patient outcomes for pulmonary rehabilitation?

Regarding PR outcomes, each of the five hospitals note that improvement in physical functioning can be measured with the six-minute walk test; quality of life and quality of health outcomes can be measured by a variety of recognized and published patient questionnaires; and utilization of services can be measured by comparing hospital admissions and average length of stays pre and post pulmonary rehabilitation services.

Is there adequate evidence, including clinical trials, for evaluating health outcomes of pulmonary rehabilitation in the Medicare population?

No hospitals answered this question.

Comments on the questions without Evidence Citation

We received 144 public comments that did not contain evidence citation. The majority of the comments without evidence citation did not directly address any of the questions CMS posed on the tracking sheet. Of the 144 comments, 115 are from patients and 2 are from people with patients in the family. Of the 144 comments, 143 were in favor of CMS covering some sort of PR program. One commenter did not clearly indicate being for or against coverage and no comments were against coverage. With regard to the questions that CMS posed on the website, 55 comments addressed the questions.

What is the appropriate definition of pulmonary rehabilitation?

Two commenters suggest a definition for PR. One states that PR is a “multidisciplinary care modality designed to maximize the life potential of patients suffering from chronic pulmonary or cardiopulmonary diseases.” The other commenter notes that PR is “a multidisciplinary program that has been shown to decrease hospitalizations, length of stay in hospital, and improve quality of life for lung disease patients.”

What are the components of pulmonary rehabilitation?

Fifty commenters addressed various components of PR including; exercise, training/education, breathing exercises, counseling, physical therapy, nutrition/diet, activities of daily living, maintenance, support groups and smoking cessation. The breakdown is as follows: thirty nine refer to exercise; fourteen mention training or exercise; thirteen discuss breathing exercises; eleven mention nutrition or diet; six suggest counseling; five cite maintenance; three mention activities of daily living; and one commenter each discuss physical therapy, support groups, and smoking cessation.

Is pulmonary rehabilitation conducted similarly in all settings?

No commenters answered this question.

What are patient outcomes for pulmonary rehabilitation?

Of the 144 commenters, three suggested patient outcomes for PR. One suggested that patient outcomes should focus on progress toward goals as established by the patient's care plan as well as measures of exercise endurance. Another commenter lists outcomes including; improved quality of sleep, building muscle strength, increased stamina, uplifted sense of wellbeing and outlook for improving health, improved communication and physical and mental strength. Another commenter suggests outcomes such as decreased hospitalizations, decreased length of stay in hospitals and improved QoL.

Is there adequate evidence, including clinical trials, for evaluating health outcomes of pulmonary rehabilitation in the Medicare population?

No comments submitted without evidence answered this question.

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act § 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." § 1862(a)(1)(A).

Definition and Components of Pulmonary Rehabilitation

All of the professional societies except for APTA cite the definition adopted in the ATS and the European Respiratory Society (ERS) 2006 Statement on Pulmonary Rehabilitation: “Pulmonary rehabilitation is an evidence-based, multidisciplinary, and comprehensive intervention for patients with chronic respiratory diseases who are symptomatic and often have decreased daily life activities. Integrated into the individualized treatment of the patient, pulmonary rehabilitation is designed to reduce symptoms, optimize functional status, increase participation, and reduce health care costs through stabilizing or reversing systemic manifestations of the disease.” We believe that this is a reasonable definition for pulmonary rehabilitation services.

In our review of the literature, the components of PR did vary. However, they generally include some or all of the following components: a medical evaluation, treatment plan development and implementation, monitoring, counseling/ education; exercise training; self-management training; nutrition training; and psychosocial support (Nici et al., 2006). As the TA and our internal assessment found, there is strong evidence to support exercise as an effective component of PR. There is a paucity of evidence regarding drawing robust conclusions on whether exercise training has an additional impact when added to other non-exercise PR components such as counseling, education or inspiratory muscle training. Part of the reason for the paucity of data is that, while there is general agreement on what the components of PR are, there is little agreement on how to standardize, measure and test the effects of the combinations of components. This has resulted in many RCTs that do not measure the same thing. Though there is generally a lack of statistically significant differences when comparing exercise training alone with non-exercise components alone, and when assessing the incremental impact of non-exercise components added to exercise training, we did find evidence to support counseling by a health care specialist in certain specified situations (De Blok et al. (2006), De Godoy et al. (2003), Steiner MC et al. (2003), White RJ et al. (2002)). There is generally insufficient evidence to draw robust conclusions on whether education or inspiratory muscle training has an incremental impact when added to exercise training.

The vast majority of evidence was found for PR in outpatient settings. For home-based PR, interventions such as patient education, enhanced follow-up, and enhanced self-management skills in patients with COPD did not result in clinically meaningful improvements in health care status and self-reported health care utilization. However, it was reported that in homebound patients $\geq$ 60 years of age with COPD, a 12 week home-based PR program was effective in improving exercise intolerance, subjective breathlessness, and QoL for housebound elderly COPD patients. Overall we found insufficient evidence to support homebound PR programs or components.

A large number of randomized controlled trials (RCT) have been reported on PR interventions in participants generalizable to the Medicare population, and most of these trials studied patients with COPD. The data we reviewed mostly applies to GOLD classification II or III (moderate or severe) COPD (Gold 2001) patients. CMS found strong evidence to conclude that that exercise-based PR is effective in improving the patients' disease-specific QoL, as well as their functional and maximal exercise capacity. This is especially true in the short term (under 12 weeks) where improvements are significantly larger than the accepted minimal clinically meaningful improvement. CMS also finds that exercise-based PR interventions may reduce hospitalizations and primary care consultations. PR is also supportive in patients recovering from or recently recovered from acute exacerbations of COPD. Therefore, the evidence is adequate to conclude that pulmonary rehabilitation improves health outcomes for persons with GOLD classification II or III (moderate or severe) COPD in ambulatory settings.

CMS did not find adequate evidence to draw conclusions about pulmonary diseases other than COPD. Therefore, we are not drawing any conclusions about the reasonableness or necessity of PR for these conditions.

The evidence also does not clearly delineate the appropriate frequency or duration of PR sessions. The AHRQ TA included RCTs that reported a variety of frequencies of exercise training, ranging from three times per week for six weeks up to five times per week for 12 weeks. While only anecdotal information, CMS has previously determined that a similar service, cardiac rehabilitation, had evidence of benefit when provided for up to 36 sessions over a maximum of 12 weeks with contractors allowed to extend the service for an additional 36 sessions over an additional maximum of 12 weeks. This is consistent with the trial data we reviewed for PR; however, it is insufficient to make a reasonable and necessary decision as to the appropriate frequencies. We invite public comments regarding frequency and duration of PR services.

Having made these evidentiary conclusions, we must now apply these to the Medicare program. In the CORF setting, CMS has outlined respiratory therapy services that are covered in a CORF. That list of services is consistent with our evidentiary findings other than the CORF does not include nutrition services. Additionally, the CORF regulations require a plan of treatment for each patient that outlines how these services would be applied to individual patients. We believe this is consistent with our evidentiary findings.

However, other outpatient settings do not include the package of benefits outlined in the CORF. Neither is there a benefit category for the combination of services that make up pulmonary rehabilitation. While some of the components of pulmonary rehabilitation do have a benefit category, others do not. Our evidentiary review did not find evidence of benefit when the services with a benefit category are provided independently to COPD patients. Thus, we are unable to make a reasonable and necessary decision on individual components of pulmonary rehabilitation provided in Medicare patients in other settings.

IX. Proposed Decision

The Centers for Medicare and Medicaid Services (CMS) proposes that the respiratory therapy services identified in the Comprehensive Outpatient Rehabilitation Facility (CORF) as defined in 42 CFR §410.100(e)(1) to (2)(vi) are reasonable and necessary in chronic obstructive pulmonary diseases (COPD) in patients with GOLD classification II or III (moderate or severe) when provided together as a comprehensive program and when the frequency and duration of each service is tailored for each patient.

CMS proposes that since the Social Security Act does not expressly define a comprehensive Pulmonary Rehabilitation Program as a part B benefit, and that the evidence is not adequate to draw conclusions on the benefit of individual components of pulmonary rehabilitation, we are not making any proposed national coverage determinations about these services at this time.

We are requesting public comments on this proposed determination pursuant to §1862(1) of the Social Security Act. We are particularly interested in comments that include input on the frequency and duration of the respiratory therapy services identified in 42 CFR §410.100(e)(1) to (2)(vi). After considering the public comments and any additional evidence we will make a final determination and issue a final decision memorandum.

Appendices [PDF, 230KB]

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